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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,731	03/04/2005	Nicole Francisca Van Poppel	I-2002-017 US	5787

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Intervet/Schering-Plough Animal Health
PATENT DEPARTMENT
PO BOX 318
29160 Intervet Lane
MILLSBORO, DE 19966-0318

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/526,731	**Applicant(s)** VAN POPPEL ET AL.	
	Examiner JaNa Hines	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 November 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *21-35*.
   Claim(s) withdrawn from consideration: *none*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Mark Navarro/
Primary Examiner, Art Unit 1645

The proposed after final amendments will not be entered because the raise new issues that would require further consideration and/or search. The new issues are drawn to the claims requiring the promoter to be switched on and off, regulating the expression of the ribosomal protein gene, whereby ribosome synthesis is limited thereby limiting parasite replication in infected cells. This limitations was not previously recited; thus the new issues in the proposed amendment furthers further search and consideration. Furthermore, the proposed amendments are not deemed to place the aplicatio in better form for appeal by materially reducing or simplifying the issues for appeal. Therefore the after final amendment will not be entered.

The rejection of claims 21, 28-32 and 34-35 under 35 USC 102(b) as beng anticipated by Wirtz et al., is maintained. The rejection is on the grounds that Wirtz et al, teach an attenuated live parasite of the phylum Apicomplexa, wherein said parasite comprises a ribosomal protein gene under the control of an inducible promoter and an immunogenic composition comprising the attenuated live parasite and a pharmaceutically acceptable carrier and a method for the production of the immunogenic composition.

The rejection of claims 21-27 and 29-31 under 35 U.S.C. 103(a) as being unpatentable over Sutherland et al., in view of Xu et al., is maintained. The rejection was on the grounds that Sutherland et al., teach the attenuation of Theileria cell lines and other avirulent apicomplexan protozoa and the desire and need to control gene expression in such parasites. Xu et al., teach the expression of genes whose products have a harmful effect and the desire and need to control gene expression in a wide variety of expression systems. Therefore it would have been prima facie obvious at the time of applicants' invention to apply the attenuated live parasite of Sutherland et al., which incorporates a ribosomal protein gene under the control of an inducible promoter as taught by Xu et al., in order to provide a significant advance in the art.

The rejection of claims 21,28-32 and 34-35 under 35 U.S.C. 103(a) as being unpatentable over Titus et al., in view of Yan et al., is maintained. The rejection is on the grounds that Titus et al., teach the development of a safe live attenuated Leishmania vaccine by gene replacement; however Titus et al., do not teach Leishmania comprising a ribosomal protein gene under the control of an inducible promoter. Yan et al., teach tetracycline regulated gene expression in Leishmania with an inducible system that provides stringent regulation of gene expression in Leishmania while offering great advantages. Therefore it would have been prima facie obvious at the time of applicants'invention to apply the attenuated live parasite of Titus et al., which incorporates a ribosomal protein gene under the control of an inducible promoter as taught by Yan et al., in order to provide more effective protective Leishmania vaccines.